K003667

FEB 1 4 2001

ATTACHMENT B - 510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Reveal® Plus Insertable Loop Recorder (ILR) System. This system is composed of the Model 9526 implantable recorder and the Model 6191 Activator. The Model 9809E Reveal Plus software, Model 9790 programmer and programming telemetry head are also part of the system.
Common Name:	Insertable Loop Recorder
Device Classification:	Class II
Product Classification and Code:	Cardiac Implantable Event Recorder (Product Code 74 MXC)(21 CFR 870.2800)

Contact Person:

Stacey Paetschow Wessman
Product Regulation Manager
Medtronic, Inc.
4000 Lexington Avenue North
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Shoreview, MN 55126-2983

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Predicate Device

The following devices are the predicate devices for the Reveal Plus:

- GBI-3S Ambulatory ECG Holter Recorder (K971670),
- DXP 1000 Holter Recorder (DigiTrakPlus)(K003618),
- Zymed Holter 2000 (K990170),
- Alaris King of Hearts Express II (K983626),
- and the Reveal Plus ILR (K994331).

Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The Medtronic Model 9526 Reveal Plus ILR continuously monitors cardiac rhythm and records subcutaneous electrocardiogram (ECG) into its looping memory upon activation (patient- or automatic-activation). The system consists of the Model 9526 implantable loop recorder and the Model 6191 Patient Activator. A Medtronic Model 9790 programmer equipped with a Medtronic Model 9766A radio frequency telemetry head and Model 9809E software is required for programming and retrieving data from the recorder.

Indications for Use

The Reveal Plus ILR is an implantable patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias.
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia.

Substantially Equivalent Devices

The Medtronic Reveal Plus Model 9526 ILR is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- GBI-3S Ambulatory ECG Holter Recorder (K971670),
- DXP 1000 Holter Recorder (DigiTrakPlus)(K003618),
- Zymed Holter 2000 (K990170),
- Alaris King of Hearts Express II (K983626),
- and the Reveal Plus ILR (K994331).

Labeling for the Medtronic Reveal Plus Model 9526 ILR is substantially equivalent to that of the predicate devices listed above.

Summary of Studies

Testing was performed in support of the original approval of the Reveal Plus ILR and was included in the Special 510(k) Document Control Number K994331.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and subsequently market clearance of the Medtronic Reveal Plus Model 9526 Insertable Loop Recorder through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Ms. Stacey P. Wessman
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K003667
Trade Name: Reveal® Plus Insertable Loop Recorder
Regulatory Class: II (two)
Product Code: MXC
Dated: November 27, 2000
Received: November 28, 2000

Dear Ms. Wessman:

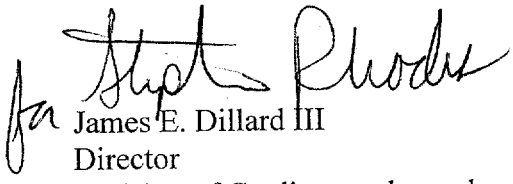
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): ~~N/A~~ K003667

Device Name: **Reveal® Plus Insertable Loop Recorder**

Indications For Use:

The Reveal Plus ILR is an implantable patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias.
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003667